Package ‘smartDesign’

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Type Package

Title Sequential Multiple Assignment Randomized Trial Design

Version 0.74

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Description SMART trial design, as described by He, J., McClish, D., Sabo, R. (2021) <doi:10.1080/19466315.2021.1883472>, includes multiple stages of randomization, where participants are randomized to an initial treatment in the first stage and then subsequently re-randomized between treatments in the following stage.

License GPL (>= 3)

Depends R (>= 4.1.0), methods, graphics, stats

Imports knitr

NeedsCompilation no

RoxygenNote 7.1.0

VignetteBuilder knitr

URL `https://cran.r-project.org/package=smartDesign`

Suggests testthat, rmarkdown

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`powerDTR` *Power Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations*

Description

Power Calculations Comparing two Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations

Usage

```
powerDTR(dtr1, dtr2, pG_A1 = 0.8, pG_A2 = 0.8, alpha=0.05)
```

Arguments

`dtr1`	an object of smartDTR class, created by function of the same name
`dtr2`	an object of smartDTR class, created by function of the same name
`pG_A1`	probability of response to therapy given assignment to A1
`pG_A2`	probability of response to therapy given assignment to A2
`alpha`	accepted type-I error rate for power calculations

Details

more details on power DTR

Value

An object of the powerDTR S3 class, with the following elements:

`powerdat:`	data.frame with sens, spec, mu, sigsq and sample size, power

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

Examples

```
mumat13 <- cbind(G1=c(30,35), G0=c(20,28))
varmat13 <- cbind(G1=c(100,100),G0=c(100,100))

dtr13 <- smartDTR(mu_Barm=mumat13, sigsq_Barm=varmat13,
                 Barm=c(1,3), nsubject=252, pG_A1=0.8)

mumat24 <- cbind(G1=c(25,32), G0=c(18,23))
varmat24 <- cbind(G1=c(100,100),G0=c(100,100))

dtr24 <- smartDTR(mu_Barm=mumat24, sigsq_Barm=varmat24,
```

```
                    Barm=c(2,4), nsubject=252, pG_A1=0.8, pG_A2=0.8)

pdtr13vs24 <- powerDTR(dtr13, dtr24)
print(pdtr13vs24)  ## plot(pdtr13vs24)
```

`powerSST` *Power for Single Sequential Treatment (SST) Trial design clinical trial calculations*

Description

Power Calculations Comparing two Single Sequential Treatment Treatment (SST) Trial design clinical trial calculations

Usage

```
powerSST(sst1, sst2, pG_A1 = 0.8, pG_A2 = 0.8, alpha=0.05)
```

Arguments

`sst1`	an object of smartSST class, created by function of the same name
`sst2`	an object of smartSST class, created by function of the same name
`pG_A1`	probability of response to therapy given assignment to A1
`pG_A2`	probability of response to therapy given assignment to A2
`alpha`	accepted type-I error rate for power calculations

Details

more details to come

Value

An object of the powerSST S3 class, with the following elements:

`powerdat:`	data.frame with sens, spec, mu, sigsq and sample size, power

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

Examples

```
sst1 <- smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=16,G0=16),
       Barm=1, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
       nsubject=252)
sst2 <- smartSST(mu_Barm=c(G1=20, G0=30), sigsq_Barm=c(G1=16,G0=16),
       Barm=2, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
       nsubject=252)

psst12 <- powerSST(sst1, sst2)
print(psst12) ## plot(psst12)
```

`smartDTR` *Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations*

Description

Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations

Usage

```
smartDTR(mu_Barm=cbind(G1=c(30,25), G0=c(20,20)),
                         sigsq_Barm=cbind(G1=c(100,100), G0=c(100,100)),
                         nsubject=500,  Barm=c(1,3), type="continuous",
                         sens=seq(0.5,1, by=0.1), spec=seq(0.5, 1, by=0.1),
                         pG_A1 = 0.8, pG_A2 = 0.8, pran_A1 = 0.5,
                         pran_Barm = c(0.5, 0.5))
```

Arguments

`mu_Barm`	matrix of two named vectors of the means for the two B arms (columns) for the smart DTR trial, with rows as 'G1' and 'G0'
`sigsq_Barm`	matrix of two named vectors of the variances (sigma-squared) for the two Blevels (columns) for the smart DTR trial, with rows as 'G1' and 'G0'
`nsubject`	total sample size for the trial
`Barm`	for the second phase of the trial, the 'B' levels for which the DTR means/variances apply
`type`	trial response variable type; only continuous is implemented currently
`sens`	range of sensitivity for smart SST calculations; (0,1]
`spec`	range of specificity for smart SST calculations; (0,1]
`pG_A1`	probability of response to therapy given assignment to A1
`pG_A2`	probability of response to therapy given assignment to A2
`pran_A1`	probability of random assignment to A1
`pran_Barm`	probability of assignment to Barms

Details

see details in the reference

Value

An object of the smartDTR S3 class, with the following elements:

`dtrdat:`	data.frame with sens, spec, mu, sigsq and sample size (n)
`sst1:`	smartSST object from the first Barm
`sst2:`	smartSST object from the second Barm
`true_mumix:`	true mu mixture
`true_sigmix:`	true sigma mixture
`mu_Barm`, `sigsq_Barm`, `Barm:`	input B-arm, mu, and sigsq for DTR

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

References

Jun He, Donna K. McClish & Roy T. Sabo (2021) Evaluating Misclassification Effects on Single Sequential Treatment in Sequential Multiple Assignment Randomized Trial (SMART) Designs, Statistics in Biopharmaceutical Research, DOI: 10.1080/19466315.2021.1883472

Examples

```
mumat13 <- cbind(G1=c(30,35), G0=c(20,28))
varmat13 <- cbind(G1=c(100,100),G0=c(100,100))

dtr13 <- smartDTR(mu_Barm=mumat13, sigsq_Barm=varmat13,
                Barm=c(1,3), nsubject=252, pG_A1=0.8)

print(dtr13)
```

`smartSST` *Single Sequential Trial design clinical trial calculations*

Description

Single Sequential Trial design clinical trial calculations

Usage

```
smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=100, G0=100),
                        nsubject=500,
                        Barm=1, type="continuous",
                        sens=seq(0.5,1, by=0.1), spec=seq(0.5, 1, by=0.1),
                        pG_A1 = 0.8, pG_A2=0.8, pran_A1 = 0.5, pran_Barm = 0.5)
```

Arguments

`mu_Barm`	named vector of the means for the Barm for the smart SST trial, with names 'G1' and 'G0'
`sigsq_Barm`	named vector of the variances (sigma-squared) for the Barm for the smart SST trial, with names 'G1' and 'G0'
`nsubject`	total sample size for the trial
`Barm`	for the second phase of the trial, the 'B' level for which the means/variances apply
`type`	trial response variable type; only continuous is implemented currently
`sens`	range of sensitivity for smart SST calculations; (0,1]
`spec`	range of specificity for smart SST calculations; (0,1]
`pG_A1`	probability of response to therapy given assignment to A1
`pG_A2`	probability of response to therapy given assignment to A2
`pran_A1`	probability of random assignment to A1
`pran_Barm`	probability of assignment to Barm

Details

more details on smart SST

Value

An object of the smartSST S3 class, with the following elements:

`sstdat:`	data.frame with sens, spec, mu, sigsq and sample size (n)
`mu_Barm:`	The value of mu_Barm passed to the function
`sigsq_Barm:`	The value of sigsq_Barm passed to the function

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

References

Jun He, Donna K. McClish & Roy T. Sabo (2021) Evaluating Misclassification Effects on Single Sequential Treatment in Sequential Multiple Assignment Randomized Trial (SMART) Designs, Statistics in Biopharmaceutical Research, DOI: 10.1080/19466315.2021.1883472

Examples

```
sst1 <- smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=16,G0=16),
       Barm=1, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
       nsubject=252)
print(sst1$sstdat, digits=2)
```

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